Institutional Handbook of Operating Procedures Policy 9.13.14	
Section: 9, Clinical	Responsible Vice President: Executive Vice President UTMB Health System
Subject: General Clinical Procedures and Care	Responsible Entity: Pharmacy

I. Title

Adverse Drug Events

II. Policy

Adverse drug events such as potential medication errors, medication errors, and adverse drug reactions shall be reported by the healthcare professional(s) involved in, witnessing, or first discovering the adverse drug event. ***This includes all actual or potential adverse drug events, which should be addressed with a positive, proactive, and educational approach geared towards information gathering with appropriate follow-up to facilitate improvement in all aspects of the medication use process.***

This policy applies to non-research related contexts only. If UTMB patients are involved in clinical research studies, the UTMB Institutional Review Board is the appropriate authority to receive reports of adverse events that occur in the research context.

III. Reporting Adverse Drug Events (ADE's)

A. All actual ADE's will be communicated to the treating provider. The treating provider is responsible for notifying the attending physician. Any ADE that results in temporary or permanent harm, or that requires additional monitoring or treatment to prevent harm, must be communicated to the attending physician immediately.

B. Information reported regarding adverse drug events is private and confidential, and must not be:
   1. shared with personnel other than those specified by the procedure below;
   2. referenced in a patient's medical record or an employee's file; or
   3. printed or copied.

IV. ADE Subcommittee Responsibilities

A. The Adverse Drug Event Subcommittee is subcommittee of the Pharmacy and Therapeutics (P&T) Committee, which reports to the Performance Improvement, Risk Management and Safety Committee (PRMS). ADE is a multidisciplinary committee established to provide oversight of the creation of safe systems within the medication use process. The subcommittee functions to analyze potential and actual ADE's, as well as create and/or recommend policy changes, and initiate appropriate staff training/education to prevent the recurrence of future ADE's.

B. All ADE's will be reported to the pharmacy for data compilation purposes. The ADE subcommittee will compile, assess and make recommendations based on data analysis.

V. Definitions

Actual Adverse Drug Event - An event in the medication use process that reached the patient and caused injury or potential injury (e.g., a medication error, or an adverse drug reaction).

Potential Adverse Drug Event - An error in the medication use process that if it had reached the patient, could have caused injury.

Adverse drug reaction (ADR) - An unintended physical reaction to a drug used in the approved manner. Allergic reactions (immunologic hypersensitivity, occurring as the result of unusual sensitivity to a drug) and idiosyncratic reactions (abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADR's. For the purpose of this policy, side effects (expected, well-known reactions resulting in little or no change in patient management) are not included in this definition.

Medication Error - Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, or systems (e.g., prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use).

Medication use process - The cycle of medication management which includes ordering, dispensing, administering, and monitoring medication use, as well as all the systems that support these processes.

VI. Relevant Federal and State Statutes

Health Care Quality Improvement Act (HCQIA). 42 U.S.C. §§ 11101-11152

VII. Related UTMB Policies and Procedures

IHOP 9.11.5 *Physician Orders*
IHOP 9.13.13 *Unusual Event Reporting*

VIII. Additional References

American Society of Health-System Pharmacists. *ASHP Guidelines on Preventing Medication Errors in Hospitals*; Am J Hosp Pharm. 1993; 50:305-14.

IV. Dates Approved or Amended

Originated: 7/20/1998	
Reviewed with Changes	*Reviewed without Changes*
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